

GYNECARE GYNEMESH* PS

Nonabsorbable PROLENE* Soft Mesh

Ikke-resorberbar blød PROLENE*-meche

Niet-resorbeerbaar PROLENE* soft mesh

Resorboitumaton pehmeä PROLENE*-verkko

Treillis PROLENE* non résorbable, souple

Nicht-resorbierbares PROLENE* Soft-Netz

Rete non assorbibile in PROLENE* morbido

Rede não absorvível PROLENE* Soft

Malla blanda PROLENE* no absorbible

Ikke absorberande PROLENE* mjuk nät

Μη απορροφήσιμο μαλακό πλέγμα PROLENE*

不可吸收的PROLENE* 柔软网片

Manufactured by:

GYNECARE 
WORLDWIDE
A division of **ETHICON, INC.**
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

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GYNECARE GYNEMESH* PS

Nonabsorbable PROLENE* Soft Mesh

ENGLISH

DESCRIPTION

GYNECARE GYNEMESH* PS is constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE* Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh.

GYNECARE GYNEMESH PS is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaption to various stresses encountered in the body.

INDICATIONS

GYNECARE GYNEMESH PS is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

INSTRUCTIONS FOR USE (APPLICATION)

It is recommended that sutures, staples or other appropriate fixation devices be placed at least 6.5 mm (1/4") from edge of the mesh. Some surgeons prefer to suture into position an uncut section of mesh that is considerably larger than the defect. When the margin sutures have all been placed, the extra mesh is trimmed away.

PERFORMANCE

Animal studies show that implantation of PROLENE mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

CONTRAINDICATIONS

When this mesh is used in infants, children, pregnant women or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

WARNINGS/PRECAUTIONS/INTERACTIONS

Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing GYNECARE GYNEMESH PS for pelvic reconstruction.

Acceptable surgical practices should be followed for the management of infected or contaminated wounds.

The use of GYNECARE GYNEMESH PS in contaminated wounds should be used with the understanding that subsequent infection may require additional surgical procedures such as removal of the mesh.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.

STERILITY

The product is sterilized by ethylene oxide. DO NOT RESTERILIZE. Do not use if package is opened or damaged. Discard opened, unused mesh.

STORAGE

Recommended storage conditions: below 25°C, away from moisture and direct heat. Do not use after expiry date.

HOW SUPPLIED

GYNECARE GYNEMESH PS is available in single packets as sterile, clear sheets with blue stripes.

